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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018
321	7590	11/30/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/803,819	SYVERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 August 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 6-11 and 14-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

Receipt of terminal disclaimer and response dated 8-17-06 is acknowledged.

Claims 1-60 are pending, claims 1-4, 6-11 and 14-25 have been considered for examination and claims 5, 12, 13 and 26-60 are non-elected and hence withdrawn.

The terminal disclaimer filed on 8-17-06 has been accepted and accordingly the double patenting rejection has been withdrawn.

***Response to Arguments***

Applicant's arguments filed 8-17-06 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 103***

1. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,470,978 to Stolar in view of US 6,416,779 to D'Augustine.

Stolar teaches a composition comprising trimethoprim, a sulfa drug and phenoxyethanol, for achieving a synergistic antibacterial effect (col. 1 and examples). Stolar however does not teach the non-absorbent articles of the instant claims.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15). It would have been obvious for one of an

ordinary skill in the art at the time of the instant invention to add phenoxyethanol of Stolar phenoxyethanol to the non-absorbent feminine devices such as tampons, intravaginal sponge etc., described by D'Augustine for treating microbial or bacterial infections in the vaginal area of females because Stolar teaches phenoxyethanol as an effective antimicrobial agent and D'Augustine suggests effective delivery of antimicrobial or antibacterial compounds through the vaginal devices to vaginal mucosa and vaginal epithelium.

**RESPONSE:** Applicants presented the same arguments that were made in the previous response dated 2-27-06, which were addressed in the action dated 5-18-06 by the examiner and which are reproduced below:

Applicants argue that Stolar teaches an antibacterial composition comprising phenoxyethanol (reads on the claimed compounds), trimethoprim and an antibacterial sulfa drug, to treat bacterial infections. It is argued that Stolar does not disclose phenoxyethanol as an antibacterial agent and only teaches the compound in a group of three compounds. In response to this, Stolar clearly suggests including a synergistically effective amount of phenoxyethanol in the total "antibacterial composition" (col. 1, lines 40-55), thus implying antibacterial property of phenoxyethanol. Applicants argue that Stolar teaches oral administration and therefore one would not be motivated to use phenoxyethanol in the non-absorbent devices of D'Augustine. In response to this, Stolar not only teaches tablets but also teaches solutions, suppositories etc., suggesting other routes of administration and therefore the argument that an oral composition cannot be combined with non-absorbent device such as tampons is moot.

It is argued that Stolar fails to teach non-absorbent substrates of the instant claims, for insertion in to vagina. However, the instant rejection is made over a combination of references and the teaching of D'Augustine has been relied upon for the claimed non-absorbent materials. Applicants argue that the combination of the teachings of D'Augustine i.e., the use of vaginal devices and antibacterial, antifungal or antiviral composition for treating vaginal infections, does not meet the requirements for establishing *prima facie* obviousness, without the blue print of applicants' disclosure. Applicants argue that the motivation to combine the above references is not convincing as to why one skilled in the art would particularly pick phenoxyethanol of Stolar from a mixture of three compounds, when D'Augustine describes numerous suitable antibacterial compositions to use with their non-absorbent devices. Applicants' arguments are not persuasive because Stolar suggests a synergistic increase in the antibacterial activity by the addition of phenoxyethanol with other two compounds. On the other hand D'Augustine teaches antibacterial compounds but does not teach the highly synergistic effect in treating bacterial infection, which is suggested by Stolar. Further, instant comprising language does not exclude the presence of the other antibacterial compounds of either Stolar or D'Augustine. With respect to the argument the exoprotein inhibiting effect of phenoxyethanol, instant claims do not exclude killing of the bacteria along with inhibiting protein nor do they recite that "good" bacteria is not killed. Further, it is to be noted that the while the ultimate effect of an antibacterial agent is killing the bacteria, such an effect includes inhibiting proteins, including exoprotein. Thus, the antibacterial teaching of Stolar is inclusive of inhibiting exoprotein.

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2. Claims 14-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,470,978 to Stolar in view of US 6,416,779 to D'Augustine and US 5,612,045 ('045).

Stolar teaches a composition comprising phenoxyethanol, trimethoprim and sulfa drugs for their antimicrobial effect (col. 1). Stolar teaches that addition of phenoxyethanol increases the synergistic effect of other antimicrobial compounds and also suggests preparing the compositions as tablets, suspensions, suppositories etc., but fails to teach the claimed devices.

D'Augustine teaches a method of treating vaginal infections by administering the antibacterial, antimicrobial compounds etc., on a vaginal device such as absorbent or non-absorbent devices including tampons, rings etc (col. 2, col. 3, and col. 7, brief description of figures).

'045 teach absorbent articles and non-absorbent articles such as catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by S. Aureus (abstract, col. 3, lines 40-60). The compounds of '045 comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). '045 teach including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5) but fail to teach the compounds of instant claim 1.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Stolar together

with ether compounds in the articles of '045 because D' Augustine suggests using non-absorbent devices for administering antimicrobial compounds to treat vaginal infections and '045 also teach administering compounds effective to treat vaginal infections by including them on the absorbent or non-absorbent devices such as tampons.

Accordingly, a skilled artisan would have expected to achieve an effective treatment of vaginal infections with phenoxyethanol of Stolar and also successfully inhibit exoprotein production by the bacterial population of vagina.

**Response:** Applicants present the same arguments with respect to the teachings of Stolar and D'Augustine, which were addressed in the preceding paragraphs. It is argued that Syverson reference does not overcome the deficiencies because it merely teaches absorbent articles such as tampons, with ether compounds and does not set forth for the first active agent of claim 1. Applicants' arguments are not persuasive because the while motivation to include the first claimed compound comes from the teachings of Stolar and D'Augustine, D'Augustine and Syverson are in the same field of endeavor i.e., to treat vaginal infections by incorporating antibacterial or bacterial exoprotein inhibitors on vaginal absorbent devices such as catamenial tampons. Thus, the motivation to combine the compounds of Stolar and Syverson flows logically with an expectation to achieve the desired antibacterial and protein inhibiting effects.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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November 26, 2006



LAKSHMI S. CHANNAVAJJALA  
PRIMARY EXAMINER